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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. | |
|-------------------------------------|----------------|----------------------|-------------------------|-------------------------|--|
| 10/615,213 | 07/07/2003 | William E. Bay | 1946/1G906-US2 | 8060 | |
| 75 | 590 06/23/2004 | | EXAMINER | | |
| DARBY & DARBY P.C. | | | KILLOS, PAUL J | | |
| 805 Third Avenue New York, NY 10022 | | | ART UNIT | PAPER NUMBER | |
| , | | | 1625 | | |
| | | | DATE MAILED: 06/23/2004 | DATE MAILED: 06/23/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------|--------------|---|--|--|--|
| Office Antique Commence | 10/615,213 | BAY ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | , | | | |
| | Paul J. Killos | 1625 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | _• | | | | | |
| 2a) This action is FINAL . 2b) ☑ This | | | | | | |
| 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | |
| Disposition of Claims | | | | | | |
| 4) ☐ Claim(s) <u>1-28</u> is/are pending in the application. 4a) Of the above claim(s) is/are withdraw 5) ☐ Claim(s) <u>2,6 and 10</u> is/are allowed. 6) ☐ Claim(s) <u>1,3-5,7-9 and 11-28</u> is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and/or | vn from consideration. | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date | 4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | | | | | |

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The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,2,4,5,7-9, and 11-28 are rejected under 35 U.S.C. 102(b) as being anticipated by WO 96/30036 published 03 October 1996.

The claimed compounds are taught throughout the reference. The disodium salts and monosodium salts are formed in situ when the compounds are treated with sodium hydroxide. The pharmaceutical composition, method of administration, etc. are clearly taught by the reference.

Claims 2, 6, and 10 are allowable if presented in independent form.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul J. Killos whose telephone number is 571-2720687. The examiner can normally be reached on Mon-Fri. 8:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, A. Rotman can be reached on 703-3084698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Paul J. Killos Primary Examiner Art Unit 1625
